

## **Preamble**

The Report on Carcinogens is mandated by Section 301 (b) (4) of the Public Health Services Act, as amended, and is for informational purposes only. The evaluation of substances listed in the Report is performed by scientists from the National Toxicology Program, other Federal health research and regulatory agencies, and nongovernment institutions. The listing of a substance in the Report is descriptive and qualitative in nature and represents an initial step in hazard identification, which is generally considered the first step in the analytical process known as risk assessment. It is necessary to conduct a risk assessment in order to estimate the potential for any substance to harm human health. Risk assessments are not conducted by the National Toxicology Program for substances in the Report. The listing of a substance in the Report, therefore, does not establish that any such substance presents a risk to persons in their daily lives. Such risk assessments are properly the purview of the appropriate Federal, State, and local health regulatory and research agencies.

For the purpose of this Report, “known to be a human carcinogens” are defined as those substances for which there is sufficient evidence of carcinogenicity from studies in humans that indicates a causal relationship between exposure to the agent, substance, or mixture and human cancer. “Reasonably anticipated to be human carcinogens” are those substances for which there is limited evidence of carcinogenicity in humans and/or sufficient evidence of carcinogenicity in experimental animals. Sufficient evidence in animals is demonstrated by positive carcinogenicity findings in multiple species, or at multiple tissue sites, or by multiple routes of exposure, or to an unusual degree with regard to incidence, site or type of tumor or age at onset. There may be substances for which there is less than sufficient evidence of carcinogenicity in humans or laboratory animals but for which there are compelling data indicating that the substances would cause cancer in humans. Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub populations, genetic effects or other data relating to mechanism of action, and/or factors that may be unique to a given substance. There may be substances for which there is evidence of carcinogenicity in laboratory animals, but there are compelling data indicating that the agent acts through mechanisms which do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans.